Docket No.: M1100,70002US00

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Gabrio Roncucci et al.

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Examiner:

P. V. Ward

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Dated: December 16, 2008

## RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Office Action mailed September 16, 2008 (Paper No. 20080911), Applicant hereby provisionally elects Group III claims for continued examination, with traverse.

The Examiner has required restriction purportedly under PCT Rules 13.1 and 13.2 and 37 CFR §§ 1.475 and 1.499 between:

> Group I: The compounds, composition, process and diagnostic agents according to claims 1-10 and 15 of formula I;

> Group II: The compounds, composition, process and sterilizing agents according to claims 1-10 and 16 of formula I;

Group III: The compounds, composition, process and method of treating, according to claims 1-10 and 19-20 and 24 of formula I;

Group IV: The compounds, composition, process and method of localizing and sterilizing according to claims 1-10 and 21-23 of formula I.

As an initial matter, it is unclear from the present Office Action whether the Patent Office has withdrawn the previous election of species requirement set forth in the Office Action of April 14, 2008 in view of Applicants' traversal thereof in their response filed June 16, 2008. Clarification is respectfully requested. If, in the next Office Action, the Patent Office does not clarify this point, Applicants will assume that the previous election of species requirement has been withdrawn and replaced by the present requirement for restriction.

The Applicants have elected Group III claims directed to compounds, compositions, and methods of treatment, but traverse this requirement for the reasons given in the paragraphs below. Prior to addressing the grounds for traversal, however, given the subject matter identified by the Patent Office as representative of the Group III category and providing the alleged basis for lack of unity set forth in the requirement for restriction, Applicants believe that, in addition to claims 1-10, 19-20 and 24 identified in the Office Action with this subject matter, claim 23 also would rightfully belongs in this group, since it is directed to a method of *in vivo* treatment of a patient (for sterilizing a wound). By contrast, the sterilization method of claim 22, which has been identified with the Group IV claims, is not directed to *in vivo* treatment of a patient. Furthermore, claim 16 directed to sterilizing agents, which may be used in the method of treatment set forth in claim 23 is also believed to be logically part of the Group III category as defined. Accordingly, even if the requirement should be maintained, Applicants respectfully request that claims 16 and 23 be examined as part of the Group III claims.

The traversal is made on the basis that all of the claims of Groups I-IV alleged by the Patent Office to define separate inventions lacking unity of invention, contrary to the position of the Patent Office, fulfill the requirement of unity of invention under both PCT Rule 13.2 and 37 CFR §1.475.

On pages 2 and 3 of the Office Action, the Patent Office states that there is no special technical feature which unites Groups I-IV to provide unity of invention.

Applicants respectfully disagree. As set forth in PCT Rule 13.2 and 37 CFR §1.475(a), "special technical features" mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art. In the present application, such special technical feature characterizing each of the pending claims and representing a contribution which each of the presently claimed inventions makes over the prior art is the compounds of formula I characterized by the presence of the specific substituent R groups set forth in claim 1.

Notably, and definitively with respect to unity of invention, this special technical feature (i.e., the chemical compounds recited in independent claim 1) is a characterizing feature common to each of the claims of Groups I-IV, since claim 1 specifically recites these compounds and all of claims 2-10, 15-16 and 19-24 depend from and include all of the limitations of independent claim 1 Nowhere has the Patent Office shown or suggested that this special technical feature common to each and every one of the currently pending claims does not define a contribution of the claimed invention over the prior art of record. Indeed, as established by the International Search Report and International Preliminary Examination of the International Application from which this National Stage application under 35 USC § 371 derives, the compounds of claim 1 possess both novelty and inventive step over the prior art of record (i.e. represent a contribution over the prior art).

Accordingly, it is believed that all of the pending claims do fulfill the requirement of unity of invention according to PCT Rule 13.2 and 37 CFR §1.475 with respect to each other by including the special technical feature embodied by the compounds set forth in independent claim 1, from which all the other claims depend.

While it has been shown above that each of the pending claims does include a special technical feature providing unity of invention for all of the pending claims, the Patent Office on page 3 of the Office Action appears to allege that 37 CFR §1.475(b) provides another independent

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basis for determining that there is no unity of invention between the claims and the groups set forth in the restriction requirement.

Applicants disagree with the apparent position of the Patent Office that 37 CFR §1.475(b) mandates an additional requirement unity of invention separate and distinct from 37 CFR §1.475(a) and PCT Rule 13.2. Rather, 37 CFR §1.475(b) by its inclusive rather than exclusive language ("Different categories of invention will be considered to have unity of invention if...") instead defines a way of applying the "special technical features" requirement of PCT Rule 13.2 in the context of claims directed to different categories of inventions (i.e., product and process claims). Accordingly, if unity of invention is clearly shown to be satisfied under 37 CFR §1.475(a) and PCT Rule 13.2, as is the case here, then 37 CFR §1.475(b) does not create a separate, unique and additional requirement for unity of invention. This is apparent from the language of 37 CFR §1.475(c), which states that if the criteria of 37 CFR §1.475(b) are not satisfied, "unity of invention might not be present". (emphasis added) This is in contrast to the language of 37 CFR §1.475(a) which states that "the requirement of invention shall be fulfilled only" when the claims share a common special technical feature, as the claims of the present application do, as discussed above. (emphasis added)

Nevertheless, even assuming for the sake of argument that the Patent Office's apparent position that 37 CFR §1.475(b) sets forth a separate and cumulative requirement for showing unity of invention, this position still does not support the requirement for restriction set forth in the Office Action. Specifically, 37 CFR §1.475(b) is not applicable to the claim groups set forth in the Office Action, because, by its terms, this section only applies when the claim groupings are directed to different categories of invention (i.e., product and process). By contrast, each of the groups set forth in the Office Action contains both product and process claims (i.e. the claims are not grouped to reflect different categories of invention). Accordingly, 37 CFR §1.475(b) cannot be applied to support the restriction requirement as presently formulated.

For all of the reasons set forth above, Applicants believe that the present requirement for restriction is improper and that all of the pending claims fulfill the requirement of unity of invention

as set forth in PCT Rule 13.2 and 37 CFR §1.475. Accordingly, withdrawal of the restriction requirement and examination of all of the pending claims on the merits is respectfully requested.

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Respectfully submitted,

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